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lubricating or dusting powder used in the glove is excluded.

(b) *Classification*. Class I.

§ 878.4470 Surgeon's gloving cream.

(a) *Identification*. Surgeon's gloving cream is an ointment intended to be used to lubricate the user's hand before putting on a surgeon's glove.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994]

§ 878.4480 Absorbable powder for lubricating a surgeon's glove.

(a) *Identification*. Absorbable powder for lubricating a surgeon's glove is a powder made from corn starch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 878.3.

§ 878.4490 Absorbable hemostatic agent and dressing.

(a) *Identification*. An absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 878.3.

§ 878.4493 Absorbable poly(glycolide/L-lactide) surgical suture.

(a) *Identification*. An absorbable poly(glycolide/L-lactide) surgical suture (PGL suture) is an absorbable sterile, flexible strand as prepared and synthesized from homopolymers of glycolide and copolymers made from 90 percent glycolide and 10 percent L-lactide, and is indicated for use in soft

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tissue approximation. A PGL suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. "Monograph for Absorbable Surgical Sutures;" it may be monofilament or multifilament (braided) in form; it may be uncoated or coated; and it may be undyed or dyed with an FDA-approved color additive. Also, the suture may be provided with or without a standard needle attached.

(b) *Classification*. Class II.

[56 FR 47151, Sept. 18, 1991]

§ 878.4495 Stainless steel suture.

(a) *Identification*. A stainless steel suture is a needled or unneedled non-absorbable surgical suture composed of 316L stainless steel, in USP sizes 12-0 through 10, or a substantially equivalent stainless steel suture, intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure.

(b) *Classification*. Class II (special controls).

[65 FR 19836, Apr. 13, 2000]

§ 878.4520 Polytetrafluoroethylene injectable.

(a) *Identification*. Polytetrafluoroethylene injectable is an injectable paste prosthetic device composed of polytetrafluoroethylene intended to be used to augment or reconstruct a vocal cord.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 878.3.

§ 878.4580 Surgical lamp.

(a) *Identification*. A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.

(b) *Classification*. Class II.

§ 878.4630 Ultraviolet lamp for dermatologic disorders.

(a) *Identification*. An ultraviolet lamp for dermatologic disorders is a device (including a fixture) intended to provide ultraviolet radiation of the body to photoactivate a drug in the treatment of a dermatologic disorder if the

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labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.

(b) *Classification*. Class II.

§ 878.4635 Ultraviolet lamp for tanning.

(a) *Identification*. An ultraviolet lamp for tanning is a device that is a lamp (including a fixture) intended to provide ultraviolet radiation to tan the skin. See § 1040.20 of this chapter.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63010, Dec. 7, 1994]

§ 878.4660 Skin marker.

(a) *Identification*. A skin marker is a pen-like device intended to be used to write on the patient's skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994]

§ 878.4680 Nonpowered, single patient, portable suction apparatus.

(a) *Identification*. A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2318, Jan. 14, 2000]

§ 878.4700 Surgical microscope and accessories.

(a) *Identification*. A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63010, Dec. 7, 1994]

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

(a) *Identification*. A surgical skin degreaser or an adhesive tape solvent is a device that consists of a liquid such as 1,1,2-trichloro-1,2,2-trifluoroethane; 1,1,1-trichloroethane; and 1,1,1-trichloroethane with mineral spirits intended to be used to dissolve surface skin oil or adhesive tape.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994]

§ 878.4750 Implantable staple.

(a) *Identification*. An implantable staple is a staple-like device intended to connect internal tissues to aid healing. It is not absorbable.

(b) *Classification*. Class II.

§ 878.4760 Removable skin staple.

(a) *Identification*. A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2318, Jan. 14, 2000]

§ 878.4780 Powered suction pump.

(a) *Identification*. A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter.

(b) *Classification*. Class II.